

PATENT COOPERATION TREATY
PCT
INTERNATIONAL SEARCH REPORT
(PCT Article 18 and Rules 43 and 44)

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MAY 12 2005

Applicant's or agent's file reference 08899427WO	FOR FURTHER ACTION see Form PCT/ISA/210 as well as, where applicable, item 1 below	
International application No. PCT/CA2005/000025	International filing date (day/month/year) 10 January 2005 (10-01-2005)	(Earliest) Priority date (day/month/year) 09 January 2004 (09-01-2004)
Applicant OTTAWA HEALTH RESEARCH INSTITUTE ET AL		

This international search report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This international search report consists of a total of 7 sheets.

☒ It is also accompanied by a copy of each prior art document cited in this report.

1. **Basis of the report**

a. With regard to the **language**, the international search was carried out on the basis of:

☒ the international application in the language in which it was filed

☐ a translation of the international application into _____, which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1(b))

b. ☒ With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, see Box No. I

2. ☒ **Certain claims were found unsearchable** (see Box No. II)

3. ☒ **Unity of invention is lacking** (see Box No. III)

4. With regard to the **title**,

☒ the text is approved as submitted by the applicant

☐ the text has been established by this Authority to read as follows :

5. With regard to the **abstract**,

☒ the text is approved as submitted by the applicant

☐ the text has been established, according to Rule 38.2(b), by this Authority as it appears in Box No. IV. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority

6. With regard to the **drawings**,

a. the figure of the **drawings** to be published with the abstract is Figure No.

☐ as suggested by the applicant

☐ as selected by this Authority, because the applicant failed to suggest a figure

☐ as selected by this Authority, because this figure better characterizes the invention

b. ☒ none of the figures is to be published with the abstract

Box No. I Nucleotide and/or amino acid sequence(s) (Continuation of item 1.b of the first sheet)

1. With regard to any nucleotide and/or amino acid sequence disclosed in the international application and necessary to the claimed invention, the international search was carried out on the basis of:
 - a. type of material
 - ☒ a sequence listing
 - ☐ table(s) related to the sequence listing
 - b. format of material
 - ☒ on paper
 - ☒ in electronic form
 - c. time of filing/furnishing
 - ☒ contained in the international application as filed.
 - ☒ filed together with the international application in electronic form
 - ☐ furnished subsequently to this Authority for the purposes of search.
2. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
3. Additional comments :

Box No. II Observations where certain claims were found unsearchable (Continuation of item 2 of the first sheet)

This international search report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons :

1. ☐ Claim Nos. :
because they relate to subject matter not required to be searched by this Authority, namely :
2. ☒ Claim Nos. : 8, 12, 13, 21, 24, 25
because they relate to parts of the international application that do not comply with the prescribed requirements to such an extent that no meaningful international search can be carried out, specifically :

Searches of claims 8, 12, 13, 21, 24 and 25 have been restricted to nucleotide sequences and kits comprising or encoding diabetogenic epitopes of gliadin isoforms or gbl1, as the claimed subject matter is only defined by functional rather than structural attributes, thereby rendering impossible a search over the entire scope of the claims.
3. ☐ Claim Nos. :
because they are dependant claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box No. III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this international application, as follows :

- indicated on extra sheet

1. ☐ As all required additional search fees were timely paid by the applicant, this international search report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying additional fees, this Authority did not invite payment of additional fees.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this international search report covers only those claims for which fees were paid, specifically claim Nos. :
4. ☒ No required additional search fees were timely paid by the applicant. Consequently, this international search report is restricted to the invention first mentioned in the claims; it is covered by claim Nos. : 1-25

Remark on Protest ☐ The additional search fees were accompanied by the applicant's protest and, where applicable, the payment of a protest fee.
☐ The additional search fees were accompanied by the applicant's protest but the applicable protest fee was not paid within the time limit specified in the invitation.
☐ No protest accompanied the payment of additional search fees.

INTERNATIONAL SEARCH REPORT

International application No.
PCT/CA2005/000025

A. CLASSIFICATION OF SUBJECT MATTER

IPC(7): C12N-15/11, C07K-7/06, C07K-16/16, A23L-1/29, C07K-14/415, C12N-15/29, G01N-33/02, G01N-33/48, G01N-33/564

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC(7): C12N-15/11, C07K-7/06, C07K-16/16, A23L-1/29, C07K-14/415, C12N-15/29, G01N-33/02, G01N-33/48, G01N-33/564

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic database(s) consulted during the international search (name of database(s) and, where practicable, search terms used)

DELPHION, ESPACENET, WEST, BIOSIS, CAPLUS, ESBIOBASE, MEDLINE, CAS REGISTRY, GENBANK. Keywords: diabetes, epitope, gliadin, wheat (storage globulin), gbl1

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	OKITA, T.W. et al. Evolution and heterogeneity of the α - β -type and γ -type gliadin DNA sequences. Journal of Biological Chemistry, 5 July 1985, Vol. 260, No. 13, pages 8203-8213, ISSN 0021-9258.	1, 3, 6, 8-12
A	- Figures 3 & 4	2, 4, 5, 7, 13-25
X	LITTS, J.C. et al. Genomic nucleotide sequence of a triticum aestivum 7S globulin (Gbl1) storage protein gene. GenBank nucleotide sequence database. Bethesda, MD: National Center for Biotechnology Information, 27 April 1993 [retrieved on 2005-04-20]. Retrieved from the Internet: <URL: http://www.ncbi.nlm.nih.gov/entrez/viewer.fcgi?db=nucleotide&val=170695 >, accession no. M81719.	1, 3, 6, 8-12
A	- cited in the application	2, 4, 5, 7, 13-25

☒ Further documents are listed in the continuation of Box C.

☐ See patent family annex.

* Special categories of cited documents :

- "A" document defining the general state of the art which is not considered to be of particular relevance
- "E" earlier application or patent but published on or after the international filing date
- "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- "O" document referring to an oral disclosure, use, exhibition or other means
- "P" document published prior to the international filing date but later than the priority date claimed

- "T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
- "X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
- "Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art
- "&" document member of the same patent family

Date of the actual completion of the international search

20 April 2005 (20-04-2005)

Date of mailing of the international search report

11 May 2005 (11-05-2005)

Name and mailing address of the ISA/CA
Canadian Intellectual Property Office
Place du Portage I, C114 - 1st Floor, Box PCT
50 Victoria Street
Gatineau, Quebec K1A 0C9
Facsimile No.: 001(819)953-2476

Authorized officer

Michael W. De Vouge (819) 997-2952

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X A	OSMAN, A.A. et al. A monoclonal antibody that recognizes a potential coeliac-toxic repetitive pentapeptide epitope in gliadins. <i>European Journal of Gastroenterology and Hepatology</i> , October 2001, Vol. 13, No. 10, pages 1189-1193, ISSN 0954-691X. - the entire document	14, 17-20 1-13, 15, 16, 21-25
X A	GIL GARCIA, J.R. et al. Development of a monoclonal antibody capable of detecting prolamine in wheat and oats. <i>Hybridomas and Hybridomics</i> , December 2003, Vol. 22, No. 6, pages 383-388, ISSN 1536-8599. - the entire document	14, 17-20 1-13, 15, 16, 21-25
X A	WO01/25793 A2 (ISIS INNOVATION (GB)) 12 April 2001 - pages 20-26	1, 3-6, 8-14, 17-22, 24, 25 2, 7, 15, 16, 23
P, X A	US2004216190 A1 (KOVALIC, DAVID K (US)) 28 October 2004 - SEQ ID NOs: 4427, 9971	1, 3, 6, 8-12 2, 4, 5, 7, 13-25
A	MacFARLANE, A.J. et al. A Type 1 diabetes-related protein from wheat (<i>Triticum aestivum</i>). <i>Journal of Biological Chemistry</i> , January 3, 2003, Vol. 278, No. 1, pages 54-63, ISSN 0021-9258.	1-25

INTERNATIONAL SEARCH REPORT
Information on patent family members

International application No.
PCT/CA2005/000025

Patent Document Cited in Search Report	Publication Date	Patent Family Member(s)	Publication Date
WO0125793 A2	12-04-2001	AU7539400 A	10-05-2001
		CA2386089 A1	12-04-2001
		EP1218751 A2	03-07-2002
		GB9923306D D0	08-12-1999
		JP2003511670T T	25-03-2003
		MXPA02003295 A	02-09-2002
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US2004216190 A1	28-10-2004	US2004031072 A1	12-02-2004
		US2004034888 A1	19-02-2004
		US2004214272 A1	28-10-2004
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...continued from Box III

The International Search authority found multiple groups of inventions in this international application, as follows:

I. Claims 1-25:

Amino acid sequences comprising diabetogenic epitopes, nucleotide sequences encoding such epitopes, antibodies reactive with such epitopes, and kits.

II. Claims 26 and 27:

Method of screening foodstuffs to identify immunogenic proteins therewithin.

III. Claims 28-32:

Foodstuffs modified to reduce or eliminate diabetogenic epitopes.

IV. Claims 33-35:

Method of screening a subject for reactivity toward food proteins.

The special technical feature linking claims of Invention I is considered to be the identification of diabetogenic epitopes, in particular those from gliadin and gbl1. Claims of Inventions II and IV are held to be distinct from Invention I in that the claimed methods as recited are generic and do not utilize or exploit said special technical feature. Claims of Invention III are held to be distinct from those of Invention I in that the claimed products of each invention are structurally dissimilar and fail to share said special technical feature.